

**Notice of Allowability**

Application No.

09/709,237

Examiner

Chih-Min Kam

Applicant(s)

COELHO ET AL.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/28/06.
2. ☒ The allowed claim(s) is/are 10,11,19-26,28,29,32-38 and 40.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

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### **DETAILED ACTION**

1. The Request for Continued Examination (RCE) filed on February 28, 2006 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

#### ***Status of the Claims***

2. Claims 10-11, 19-26, 28, 29, 32-38 and 40 are pending.

Applicants' amendment and Declaration of Dr. Hauria I. Hassouna filed February 28, 2006 are acknowledged. Applicant's response and Declaration of Dr. Hauria I. Hassouna have been fully considered. Claims 10, 19, 22-25 and 34-37 have been amended, and claims 14, 15, 27, 30, 31 and 39 have been cancelled. Claim 12 is a non-elected invention, thus withdrawn from consideration. Therefore, claims 10-11, 19-26, 28, 29, 32-38 and 40 are examined.

#### **Withdrawn Informalities**

3. The previous objection to Figs. 5-12 is withdrawn in view of applicant's submission of the formal drawings filed February 28, 2006.

#### **Withdrawn Claim Rejections - 35 USC § 112**

4. The previous rejection of claims 10-11, 14, 15 and 19-40 under 35 U. S. C. 112, first paragraph, is withdrawn in view of applicant's amendment to the claim, applicant's cancellation of the claims, and applicant's response at page 7 in the amendment as well as Declaration of Dr. Hauria I. Hassouna filed February 28, 2006; and Examiner's amendment (see below).

#### **Examiner's Amendment**

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR

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1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Audrey A. Millemann on March 21, 2006.

**Examiner's Amendments to the specification:**

Please replace the paragraph at page 2, line 1 inserted in the preliminary amendment filed November 10, 2000 with the following paragraph:

This application is a divisional of U.S. application serial number 09/129,988, filed August 5, 1998, now U. S. Patent No. 6,274,090.

**Examiner's Amendments to the Claims:**

Cancel claim 12.

Claims 10 and 19 have been amended as follows.

Claim 10 (currently amended)      A thrombin composition free of fibrin clots,  
consisting essentially of:

Plasma;

Ethanol (EtOH), wherein EtOH is present at a concentration between 8%  
and 18% by volume; and

CaCl<sub>2</sub>, wherein CaCl<sub>2</sub> is present at a concentration between 0.011  $\mu$ M and  
/ 0.045  $\mu$ M;

whereby particulate matter in the composition has been substantially depleted of the  
~~particulate matter sequestered~~ by filtration.

Claim 19 (currently amended)      A thrombin composition free of fibrin clots,  
consisting essentially of:

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Plasma;

Ethanol (EtOH), wherein EtOH is present at a concentration between 8%

and 18% by volume; and

a source of calcium ions, wherein calcium ions are present at a concentration between 0.011  $\mu$ M and 0.045  $\mu$ M;

whereby particulate matter in the composition has been substantially depleted of the ~~particulate matter sequestered~~ by filtration.

The following is an **Examiner's Statement of Reasons for Allowance**: The following reference appears to be the closest art to the claimed invention. Hirsh *et al.* (U. S. Patent 5,643,192) teach an autologous thrombin is prepared by cryoprecipitation of plasma to obtain supernatant plasma containing thrombin, adding calcium chloride to the supernatant plasma to form fibrin clot and thrombin, and filtering the fibrin to generate thrombin in the serum. The thrombin generated in Hirsh *et al.* achieved rapid clotting of fibrinogen (i.e., less than 5 seconds) only during a short of period of 4-5 minutes. Hirsh *et al.* does not teach or suggest a thrombin composition free of fibrin clots, consisting essentially of plasma, EtOH (8-18% by volume) and  $\text{CaCl}_2$  (0.011-0.45  $\mu$ M), whereby particular matter in the composition has been substantially depleted by filtration (see Fig. 8; page 11, last paragraph in the specification), and the thrombin composition produced in the instant application will provide fast clot (<5 seconds) throughout 360 minutes. Therefore, the claims are allowable over the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner



**CHIH-MIN KAM**  
**PATENT EXAMINER**

CMK

March 21, 2006